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ZENTRAL STERILISATION

Are Processed Surgical Instruments Free of Protein?

Results of the clinical multi-centre residual contamination study of processing (MRSA)

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In a first national clinical multicentre study the invisible residual contamination of different surgical instruments with blood and proteins after cleaning was assessed. The study was designed as a prospective observation study to analyse the actual situation. It was shown that using 2 semi-quantitative and one quantitative method, residual protein or blood could be detected in a considerable proportion of eluat specimens. These findings do not allow for a statement with regard to endangering patients. It does, however, emphasise the need for the development of a method which allows for an evaluation of cleaning efficiency, to ensure process validation for all steps of sterile supply processing.

Introduction

How free of potentially dangerous (for the patients) contaminations are any, apparently clean, surgical instruments after cleaning and before the final sterilisation step? To date, there have been only very few clinical investigations of this matter (1, 2, 3, 4, 6, 9, 13, 14, 16, 17, 18, 19).

Right up to the present day, quality control and verification of cleaning are conducted in clinical routine only on the basis of visual and tactile examination. The Medical Devices Act (MPG) stipulates that processing of medical devices be documented (validated procedure) (10). To date, this has been confined primarily to provision of evidence of compliance with the conditions of the sterilisation process, the very last processing step. But all steps from the time the contaminated instruments are handed in until they are packed and finally sterilised must be evaluated and conducted in a reproducible manner (leading to a successful outcome) and documented. Therefore it must be possible to evaluate the cleaning performance and instrument-specific implementation during automated procedures. So far, it is still quite unclear which evaluation method can be used in future in clinical routine, and which analytical methods will be accepted.

A Standard specifying general performance requirements is currently being drafted as prEN ISO 15883-1 (12). As in the case of the British model, for evaluation of the cleaning performance it has been assumed that all contamination originating from the patient and to be removed by cleaning is in some way of a protein-containing nature. Therefore in addition to visual inspection of cleaning, the method of choice is deemed to be an evaluation or a measurement based on protein analysis. Investigation of cleaning with the hitherto in Germany customarily employed method of biological indicators does not furnish correct information on the cleaning performance, because after exposure to the entire procedure it cannot distinguish quantitatively between the magnitude of microbial reduction attributable to elution and rinsing off and of that mediated by killing (15).

In industrial production, if not 100% checks, then certainly spot checks are carried out. In the meantime such checks can also be conducted in the Central Service Department, the "production department", for objective evaluation of the extent to which instruments are amenable to cleaning followed by an analysis of the existing weak links. (Quality control, higher level of safety for sterilisation and reuse of instruments for the patient).

To test the efficiency of a cleaning procedure, a test soil must be selected which is representative of the most difficult to remove soil but is nonetheless of practical relevance. Within the framework of validation of cleaning procedures, proof should be furnished that this continually produces with a high degree of certainty during instrument processing (in practice) a product which meets the previously defined specifications and quality features (here in respect of the extent of absence of protein). Whether the various components of the test soils contribute to this must for now be deemed questionable and must be proven by means of validation of the test and measurement method. Blood contaminants are of course highly relevant in practice but in addition to blood other important soils such as mucus and fats must be mentioned, which can occur while mixed in any arbitrary proportions and seal off, and thus protect, pathogenic substances and organisms against disinfection and sterilisation measures.

The aforementioned Standard at present makes no provision for the use of process challenge devices. The cleaning chamber wall, elements of the inserts and trays and a selection of the instruments for which the process is usually intended must be soiled accordingly. Challenge devices are not able either to represent the myriad different constructional features of the instruments with regard to their amenability to cleaning. Qualitative and semi-quantitative methods must be evaluated on the basis of quantitative methods. All test soils must, however, be of relevance in the clinical setting.

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The aim of this study is to first of all conduct in phase I an analysis of the actual situation with regard to contamination with protein as well as to elucidate problems relating to the study design and progression. Based on the results and experience gathered here, the ensuing phases can be planned and conducted. Once the measurement series of all phases, which still have to be planned, have been completed it should be possible to define a "cleanliness" limit value for the various methods for evaluation of cleaning.

Materials and Method

This clinical observation study (actual assessment) was carried out in 5 centres for processing sterile supplies. (One of the centres moved to a different location in the course of the study; accordingly, the graphics below show 6 centres). Investigated were 6 different instrument types (speculum, coarse Wertheim clamp, trocar sleeve, trocar flap valve, functional part of sharp tweezers (MIC), bone file – 8 specimens of each instrument type) with regard to the process parameters.

These included precleaning with ultrasound, the cleaning agent/disinfectant used (with/without neutralising agent) the type of washer-disinfector, the program. Of decisive importance for the results of the elution methods is to what extent the test solution contained particles (ideally, no particles). Only those instrument eluate specimens that contained no visual contaminants were included for assessment.

An instrument docket for documentation of these parameters was issued and evaluated for each instrument type (n = 8) by the Surgical Instruments Working Group (CIA) of Moabit Hospital Berlin. This was intended as a means of unequivocally describing each eluate.

Visual inspection, haemoglobin test and modified biuret method were conducted directly in the respective centre. The OPA method was carried out in the Bioprocess Technology Department of the Hanover Polytechnical College (Prof. Dr. H. Frister) and at the Miele premises in Guetersloh (Dr. W. Michels). To this effect, 1 ml of the eluate was frozen and dispatched under a code name.

The aim was to study the practicability and comparability of findings of three different methods available for evaluation of cleaning after SDS elution of surgical instruments (11).

- haemoglobin test
- modified biuret method
- modified OPA method

Remark: It was not possible to test the qualitative ninhydrin method because the swabs showed an intrinsic reaction. In chemistry this method is employed in paper chromatography for detection of minute amino acid quantities. Ninhydrin is a triketo compound and condenses with the amino group of an amino acid during carbon dioxide cleavage, giving rise to a reddish purple to reddish blue dye of complex formation. The change in colour is unequivocal for all amino acids apart from cyclic proline, which results in a yellow colour. The specificity of detection, the sensitivity and the unequivocal colour are not assured for (non-hydrolysed) proteins. The colour reaction is pH and protein dependent. Often the only result obtained is a non-specific yellowish or brownish colour, which can lead to false negative results when incorrectly evaluated [Michels].

In the Health Technical Memorandum (HTM) 2030 of the British National Health Service (NHS) the ninhydrin method is also listed and recommended. It even cites a reference (Analytical Biochemistry 1993; 211: 240–241). This, however, refers to the quantitative determination of chitosan and the proportion of free amino groups in chitosan samples. Dealt with here are glucosamines rather than proteins, hence it has nothing to do with the issues involved here. There is a paucity of studies on employment of the method with different test soils.

Haemoglobin Test

This involves a tried and tested in vitro diagnostic agent (Sangur Test, Boehringer, Mannheim), which is normally used for urine diagnosis. The pseudoperoxydase reaction takes place on a test strip in the presence of haemolysed erythrocytes. This is followed by immersion in the eluate and shaking off of liquid. Discoloration takes place in accordance with the degree of haemolysis, and the result is read either from the erythrocyte table or from the haemolysed-particle table (homogeneous field) in the range of 10 – 250 erys/ml.

Modified Biuret Method

On the occasion of Forum 2000 at the MEDICA exhibition, a newly developed test kit was presented (Miele, Gueterstoh). Proteins in the elution solution are measured semi-quantitatively by means of the biuret reaction, which is commonly used in biology and chemistry. However, this method has been modified to ensure good storage stability of the reagents while precluding any interference by the detergent solution (SDS elution).

This modification changes the reaction with protein also as regards the change of colour compared with the well-known biuret reaction: proteins (compounds with at least two peptide bonds) produce a violet complex with Cu^{2+} ions in an alkaline solution. In the case of this modified test kit, a Cu^{2+} solution is presented in the vessels and after addition of the test solution (SDS eluate), the copper (II)-protein complex is formed. Then with reagent 2 the superfluous Cu^{2+} is reduced to Cu^{+}, which forms with reagent 3 a red violet complex (concentration inversely proportional to the protein concentration).

To verify successful cleaning of an instrument, the surface (inner and/or outer) is repeatedly rinsed off with as small a quantity as possible (5 ml) of a detergent solution (1% SDS = sodium dodecyl sulphate), thereby causing the majority of any proteins present to go into solution. One millilitre of the solution is placed in one of the vessels containing the reaction solution. After 5 minutes a pulverised reagent and one drop of reagent solution are added with a micro spoon. If a red violet colour is then obtained, this confirms that the rinsed surface was free of protein, a less pronounced colour to colourless solution attests to an increasing protein content. If there is more than 90 mg equivalent bovine serum albumin the solution is colourless, thus being a strong indication of protein contamination (four-field table).

Modified OPA Method

With this method that has been in use for many years in the milk-processing industry the α and ε terminal amino groups of the proteins are acquisitioned (7, 11). In a stoichiometric reaction with the reagent o-phthaldialdehyde, the latter are converted in the presence of a thiol component under defined conditions into iso-indoles that can be detected by means of photometry at 340 nm. An understanding of the chemical influences and of the photometric measurement method is important when carrying out this.

Sampling is also by means of rinsing (elution) of the entire instrument surface (inner and/or outer) with as small a vol-

ume as possible (e.g. 5 ml) of 1% SDS (sodium dodecyl sulphate) solution to avoid unnecessary dilution with regard to the consecutive measurement of protein content. Thanks to its denaturing action, SDS is a powerful detergent for unfolding and dissolving proteins. Therefore it is commonly employed for protein analysis.

This type of sampling, however, rules out other analytical methods such as the Bradford, Lowry, eosin and, depending on the chemical formulation of the reagents batch, also the biuret method (SDS-compatible test kits for semi-quantitative determination for the last method mentioned are already available or are being developed. But their use is not recommended for quantitative determination because saccharose, which is present in mucus, acts as an interference substance with the biuret method).

Depending of the type of the chemical reaction, all methods entail interference factors that can potentially adversely affect detection of any proteins present. This holds true also for methods utilising isotopes (8, 16), and especially for aldehydes, which can chemically mask the amino groups to be identified (5). Furthermore, it must be noted that with the methods based on the formation of coordination complexes, different protein binding constants are manifest depending on the type of protein and on its denaturation state and lead to non-reproducible findings. However, for automated processing of surgical instruments we assume that dry transportation is assured because pretreatment with aldehydes would in principle lead to cleaning problems associated with fixation.

There is no point in engaging in quantitative determination of something which is obvious visually. Of special importance during sampling is a reasonably high recovery rate for any proteins present. Depending on the instrument type the elution method must be modified and controlled, bearing in mind in particular that the detachment process is time dependent. A high recovery rate is important primarily in the boundary region of the cleanliness to be defined and can be achieved with the SDS elution method. The smaller the layer thickness of the blood soil, the less the fibrin cross-linking and contraction of the coagulum and the better the protein solubility, so that a higher recovery is possible. Detachment of blood incrustations can be facilitated by alkalisation of the SDS solution to pH = 11. But it must be ensured that these reaction conditions do not alter the OPA method.

The OPA method is a laboratory method that must be carried out by trained personnel. It must in particular be ensured that the test volumes to be measured for each OPA batch are exactly equal, have been well mixed and have no turbidity or particles. The OPA reagent must be freshly prepared daily and measurement conducted in tested, clean and dry quartz cells. Furthermore, the blank value as well as the intrinsic extinction of the test sample must be taken into consideration. Measured values should be read only when the extinction is constant. As the OPA method is highly sensitive, duplicate tests should ideally be carried out and if extinction values are very low it may be necessary to check by means of duplicate additions of the test quantity whether there is at all OPA sensitivity (corresponding elevation of extinction /Lambert-Beer law.

The subject of cleaning addresses completely novel demands to the laboratory methods and to method validation compared with the microbiological investigations conducted hitherto for checking the disinfection performance and calls for a different knowledge and chemistry and analytical technology.

Results

Remark: The lectures volume of Forum 2000 Instrument Processing Investigation of the Automated Cleaning Performance (at the Medica exhibition in Duesseldorf, 24.11.2000) contains a detailed description of the statistical evaluation (descriptive data analysis). The addresses of the members of the Working Group Cleaning in (Automated) Processing (IRA) can also be found there.

Description of Data

48 samples were examined for each centre, altogether 240 samples (8 samples from each 6 instrument types). 219 samples were evaluated, of which 202 (92%) were classified on the basis of visual-tactile examination as "clean", 14 samples (6%) as "contaminated" (evaluation of 3 samples was not documented).

Recognition of particles was not always unequivocally documented on the instrument docket. 179 samples (82%) were unequivocally documented, this information could not be unequivocally interpreted or was missing completely for 40 samples (18%). 159 samples (89%) were free of particles, particles could be detected in 20 test solutions (11%).

The results of the haemoglobin test of a total of 176 test solutions (80%) provided no information for 43 test solutions (20%) (or the information given could not be interpreted). Of the 176 test solutions that could be interpreted, 153 (87%) were evaluated as negative (value "0 erythrocytes"), 23 test solutions (13%) were evaluated as positive: in 4 cases (2.3%) the information provided stated "5 – 10 erythrocytes", in each case 6 solutions (3.4%) were evaluated as having "≤ 10 erythrocytes" or "50 erythrocytes" and 7 samples (4%) were classified as having "250 erythrocytes". Hence based on the haemoglobin test, the vast majority of the test solutions evaluated, in total 87% (153 samples), were "clean"

In the biuret method, interpretable information was available for 197 (90%) of the 219 test solutions, no information was given for 22 samples (10%). Only 64 samples (33%) were evaluated as negative, 15 samples (7.6%) were described by means of the given information as "0 – 30", 58 samples (29%) were evaluated as "30", 6.6% (13 samples) as "30 – 60", 35 samples (17.8%) were classified with the value "60" and 12 samples (6.1%) were given the highest value with "90". Only 32.5% of the test solutions (64 samples) were accordingly judged to be "clean". 67.5% of the test solutions (133 samples) were classified as "containing protein".

The results of the modified OPA method could be evaluated for 210 of the 219 test solutions (96%). To facilitate illustration, the results were summarised in two classes: values ≤ 0.01 (detection limit) are deemed "clean", values > 0.01 are interpreted as being an indication of proteins. Based on this division, 95 test solutions (45%) were judged to be "clean", and 115 samples (55%) as "containing amines" which means that they contain OPA-sensitive (primary) amines.

Whether preliminary cleaning with ultrasound had or had not been conducted may have exerted an influence on the success of cleaning. In this respect, infor-

mation was available for 211 (96%) of the 219 test solutions. Ultrasound had been used for 106 samples (50.2%), while in the remaining 105 cases (49.8%) preliminary cleaning with ultrasound had not been carried out.

Comparison of the Analytical Methods

If one wishes to compare the results obtained for the three diagnostic methods, this is possible only for rinsing solutions (eluates) for which all tests were actually conducted (haemoglobin test, modified biuret method, modified OPA method). 150 (68.5%) of the 219 test solutions meet the aforementioned criteria: no visual-tactile contamination detectable, in addition to interpretable results from the haemoglobin test, biuret method and OPA method.

For 138 (92%) of the 150 test solutions information was available on recognition of particles in the solution. Particles could be detected in 12 solutions (8.7%), the remaining 126 test solutions (91.3%) were free of particles. Precleaning with ultrasound had been carried out for 59 instruments (39.3%), while no precleaning with ultrasound had been done for 91 instruments (60.7%).

In the haemoglobin test for the 150 test solutions (which meet the analytical criteria) the majority of the test solutions, totalling 90.7% (n = 136), were classified as "clean" ("0 erythrocytes" or negative), 9.3% or 14 test solutions were judged to be contaminated: 3 eluates (2%) "250 erythrocytes", 3 eluates (2%) "50 erythrocytes", 5 eluates (3.3%) "≤ 10 erythrocytes", 3 eluates (2%) "5 – 10 erythrocytes"

In the modified biuret method 52 (34.7%) of the 150 samples were classified as negative, 15 samples (10%) were evaluated as "0 – 30", 56 samples (37.7%) as "30", 12 test solutions (8%) as "30 – 60", 13 samples (8.7%) as"60" and 2 test solutions (1.3%) as "90", the poorest evaluation assigned in the modified biuret method. Hence based on the modified biuret method, 52 samples (34.7%) were classified as "clean", and 98 samples (65.3%) as "contaminated".

In the modified OPA method 53 samples (35%) were evaluated as "clean", and in line with the specified criteria 97 samples (65%) were classified as "contaminated"

The three methods reach different conclusions. The results of the modified OPA method and of the modified biuret method show extensive similarity in respect of the rough classification into "clean" (OPA method and modified biuret method 35% in each case) and "contaminated" (approx. 65%), whereas the haemoglobin test reaches an essentially different conclusion with evaluation of 91% of the samples as "clean" and 9% of the samples as "contaminated" However, this statement does not mean that the OPA method and the modified biuret method evaluated the same samples as "clean" or "contaminated".

Statistical Evaluation of Concordance of the Three Test Methods

To be investigated now is to what extent the three methods concordantly evaluate the same test solutions in respect of "cleanliness" To make such a comparison it is necessary in the case of qualitative or semi-quantitative methods that all methods use the same number of categories. Therefore the results of the modified biuret method and haemoglobin test were summarised in three categories. For the OPA method the results above the detection limit (> 0.01) were summarised – for statistical and methodological reasons – in two categories.

This newly defined ordinal variables offer an opportunity to statistically analyse the three methods for correlation between their results. As a significance level for the generalisability of the results of the statistical tests, a margin of error of $p < 0.05$ was specified. Using Kendalls coefficient of concordance, a check was

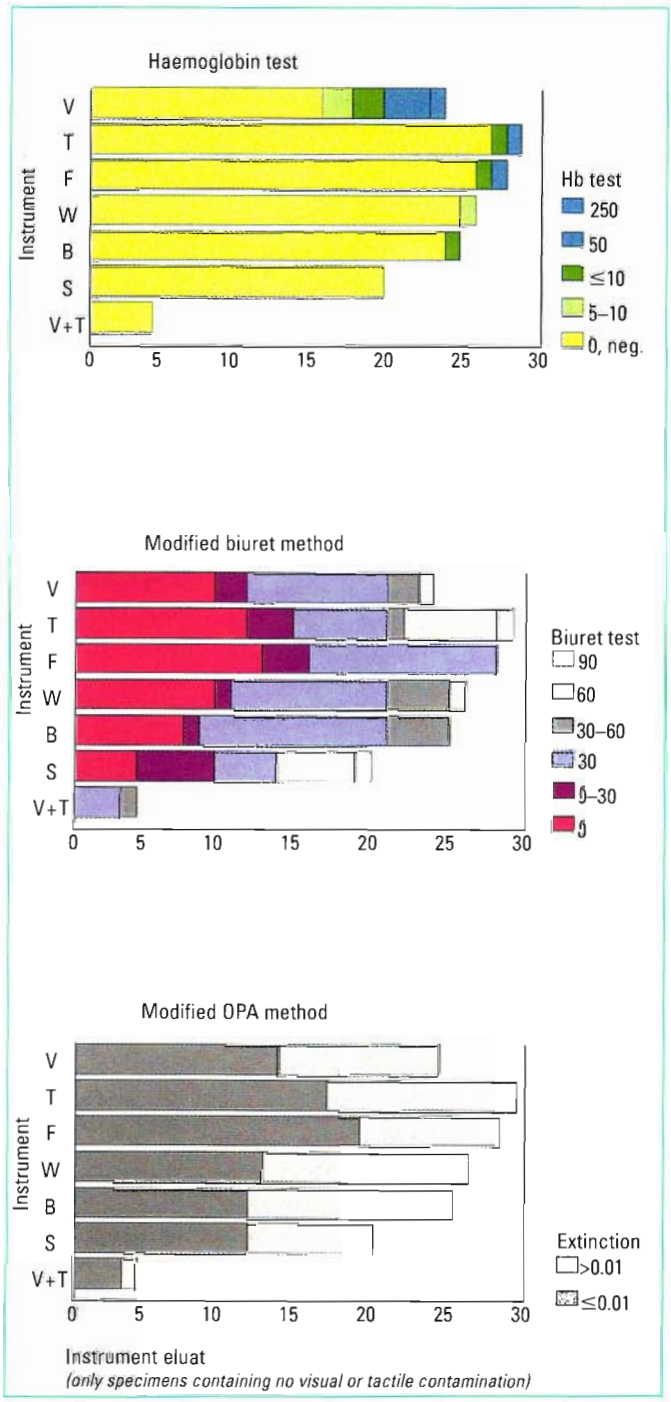

Fig. 1 Results of the three methods according to instrument types (n = 150)
V = trocar flap valve, T = trocar sleeve, F = functional part of sharp tweezers (MIC), W = coarse Wertheim clamp, B = bone file, S = Speculum
V + T: in one centre, trocar sleeve and trocar flap valve were investigated as a unit

first conducted to establish to what extent the results of all three methods are in concordance. Kendalls W is a coefficient for checking the quality of concordance between several dependent ordinal variables, which can assume values in the range 0 to 1.The value 1 indicates perfect concordance, the value 0 no concordance. As from a value of 0.6, concordance can be judged as being good. With a value of .35 ($p < 0.001$), concordance between the 3 methods is judged to be moderately positive.

As a next step, 2 methods were compared in each case in the form of contingence tables and the coefficient of concordance kappa was calculated as well as Kendalls tau-b as a correlation coefficient. Kappa is a coefficient for evaluation of the quality of concordance between two qualitative variables. The kappa value varies between 0 and 1, with the value 0 indicating no concordance and the value 1 complete concordance. As from a kappa value of 0.6, good concordance can be assumed. With a kappa value below 0.1, concordance between the results of the methods is very poor for the given data.

The correlation between two ordinal variables can be checked statistically with Kendalls coefficient tau-b. This coefficient is suitable if – as here – there are several so-called "ties" (similar value expressions). Tau-b can assume values in the range – 1 to + 1. 0 indicates no correlation between the checked variables, the value 1 denotes perfect correlation. A negative sign means that low values of one variable are accompanied by high values of the other variable. Positive means that high values for one variable appear together with high values for the other variable, and correspondingly low values are also paired with low values. As from a value of 0.6, one can talk about a moderately strong correlation between two variables.

One cannot talk about a correlation between the results of the three methods in a statistical sense (< 0.25). In terms of result it can be noted that the haemoglobin test with the highest number of negative values demonstrates reactions distinctly different from the other methods. The modified OPA method and the modified biuret test based on the biuret method show similar results with regard to the number of positive and negative results, however evaluation of these two methods do not to a large extent concord.

All three test methods detect different compounds or chemical structures in the eluates, respectively. At the margin of cleanliness and sensitivity of measurement, where clinical significance has at all to be questioned, even greater differences can be expected. Moreover, there may be a certain number of (subjective visual) misinterpretations due to the very small colorimetric differences in the biuret method at the margin negative – weakly positive.

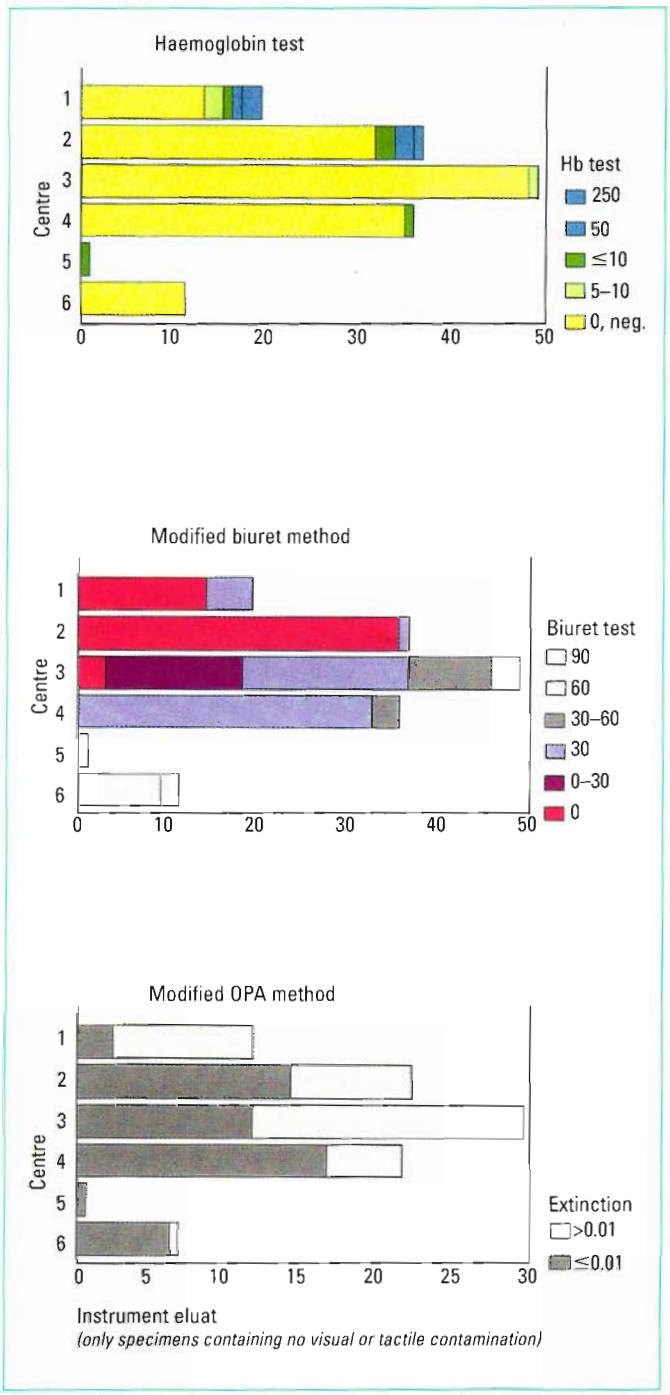

Fig. 2 Results of the three methods according to centres (n = 150)

Statistical Evaluation of the Influence of the Instrument Design

With the exception of the trocar flap valve, more than 90% of the sample solutions from all instruments were deemed "clean" only in the haemoglobin test. Only 66% of the test solutions for the trocar flap valve were evaluated as "clean", in 4 test solutions (17%) 50 and 250 erythrocytes were detected.

Judged to be "clean" in each case were about 36% to 44% of the test solutions from the trocar flap valve, the trocar sleeve, the functional part of the sharp tweezers and the coarse clamp (Wertheim). 29% of the test solutions from the bone file were judged to be "clean" and 21% from the speculum. Finally, none of the four test solutions from the combination of trocar sleeve and trocar flap valve was rated "clean".

The trocar flap valve and trocar sleeve were judged similarly: in each case approx. 30% of the test solutions were deemed "clean" In the case of the speculum, 37% of the test solutions were classified as "clean", this applied for 40% of the course clamps (Wertheim) and 52% of the functional part of the sharp tweezers. Conversely, only 25% of the test solutions from the

bone file were evaluated as "clean". In the combination trocar sleeve and trocar flap valve none of the four samples was judged as "clean". Further analyses of the correlation and concordance between the results of the three methods based on the instrument types do not appear meaningful due to the small number of cases.

Figure 1 shows the evaluations assigned to the three methods for the instrument types, Figure 2 shows the results grouped according to centres. The figures refer to 150 test solutions that had been evaluated after visual and tactile examination as "clean" and for which the results of all three diagnostic methods were available.

Discussion

Phase I of the multi-centre residual contamination study of processing (MRSA) investigated various types of instruments typically used in surgical disciplines with a different clinically mediated baseline soil. The aim was to conduct an actual assessment and measure what hitherto had not been measured: how much and what kind of contamination can be rinsed off in the Central Service Department under clinical conditions from an instrument classified after visual and tactile examination as "clean"?

To this effect, three methods were employed to evaluate cleaning. Each method refers to a different component of clinically relevant residual contamination: haemoglobin (Sangur), peptide bindings (biuret), primary amine (OPA). Of the 219 elutions carried out, it was possible to evaluate 150, for which results were available for all three test methods and which had been evaluated after visual and tactile examination as being "uncontaminated", i.e. only "clean" instruments must be tested with elaborate methods for potentially invisible and non-tactile contamination. Accordingly, comparative evaluation was confined to those samples classified after a visual-tactile check as "uncontaminated" (inclusion criterion).

Not taken into account was

- whether particles could be detected in the test solution
- whether precleaning had been conducted with ultrasound
- that different washer-disinfectors with different programs and different cleaning agents had been used.

But these parameters can affect the results of the tests to a greater or lesser extent. To take systematic account of these factors during evaluation, a much greater number of samples would have had to be used.

Depending on the instrument and design, there were also non-liquid components (particles) which could not be evaluated with these methods. However, information was often lacking on this aspect; it must also be taken into consideration that in the everyday clinical setting particles in the solution may not at all be detected or may be stuck inside the instrument. Information on particles was therefore not taken into account for evaluation of the phase I data. The influence exerted by existing visible or invisible particles on the results of the three methods can be analysed systematically only in the laboratory.

The following points rendered data interpretation more difficult from a statistical-methodological viewpoint:

- The instrument docket as well as the instructions for filling in the latter proved to be too imprecise for uniform evaluation of the data. For all tests that have to be implemented and do not as in the case of the OPA method "automatically" lead to a quantitative result, a uniform categorisation schema should be devised before beginning the study by all investigators participating in it. The information provided by the investigators on the instrument docket did not lend itself to unequivocal interpretation and was often incomplete.

- Too many subgroups give rise to interpretation problems. The smaller the number of cases, the smaller should be the number of potential subgroups. Restriction: only instruments deemed "clean" after visual and tactile examination should be investigated; either all samples with or all samples without ultrasound, neutralising agent etc., also the machine type, program type or the cleaning agent can influence the cleaning outcome, hence too many types should not be used.

- It is important that the instruments used for testing should all come from different wash cycles. The results of the instruments from one load are not independent of each other: the machine or the cleaning agent may "fail", the instruments in one wash cycle may transfer the contaminant etc.

- Apart from these systematic influences, which can be minimised or eliminated with an optimised design and correct test procedure, errors occur in every form of data survey which to an extent can be minimised but hardly eliminated. To be mentioned here is one form of bias that is introduced by the elution itself or by the investigator. The influence generated by the clinical soil itself is of course very serious. Its extent and variation cannot be evaluated. Accordingly, attention must be paid to ensuring that the influence of other factors is kept to a minimum.

Positive results in respect of clinical residual contamination of different instrument surfaces do not permit an insight into the clinico-pathological relevance, and certainly not in the case of nosocomial infections. In order to be able to elucidate causal relationships between contaminated instruments and diseased patients, another study design is required ("missing link").

Due to the large number of instruments used in an operation as well as to the host of other factors influencing the outcome (particles in the OT air, wet facial masks, non-sterile procedures during and after the operation), studies investigating these relationships will rarely lead to unequivocal results (19). Epidemiological studies, on the other hand, often have to rely on "soft" data, e.g. from patients' files, and can be interpreted in multiple ways. Insecurities with regard to the process quality in a certain hospital can therefore only be dispelled by validation of the specific processes as a means of quality assurance.

The statements made here on the actual situation of sterile supply processing should now lead to phase II of the study, during which the clinical actual assessment would be continued with one single instrument type (forceps). Ultimately, the aim is to verify the cleaning performance. In addition to recording the physical and machine-specific parameters a documentation of the cleaning performance itself is necessary. ❄

Acknowledgement

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For references please see page 26